



RÉPUBLIQUE OF CAMEROON  
*Peace - Work - Fatherland*

# CAMEROON NATIONAL LABORATORY POLICY

2022 Edition

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**2022 EDITION**

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# PREFACE

The Government, through the National Development Strategy 2020-2030, aims to strengthen the Cameroonian health system in all its components by 2030. Improving the quality of health care delivered to the population requires the establishment of an efficient laboratory system capable of providing quality services in accordance with relevant standards. It is on the strength of this observation, and as a prelude to the advent of universal health coverage in our country in accordance with the recommendations of the World Health Organization and Africa CDC, that this **NATIONAL LABORATORY POLICY** has been developed

This important document, obtained at the end of a long process of gradually broadened and multi-sector consultation, is now the compass of the Government's actions in terms of laboratories. It brings together the main political orientations that Cameroon plans to implement in its health system with a view to continuous improvement of the quality of medical laboratories services for better patient care in accordance with the **Health System Transformation Agenda: Time to act.**

I invite all actors in the health system to take ownership of this document and to be fully involved in its implementation to achieve the expected result.

I undertake and I will spare no effort, for its implementation. /-

The Minister of Public Health



The seal is circular with a red border. The outer ring contains the text 'REPUBLIC OF CAMEROON' at the top and 'LE MINISTRE DE LA SANTE PUBLIQUE' at the bottom. The inner ring contains 'LE MINISTRE DE LA SANTE PUBLIQUE' at the top and 'The Minister' at the bottom. The center of the seal features a stylized emblem. A blue ink signature is written over the seal, and the name 'D. Nkomo Molachie' is printed in red below the signature.

# ACKNOWLEDGEMENTS

This document is the result of a long process aimed at providing Cameroon with a compass to serve as a guide for the drafting of strategies and operational plans for the development of the national laboratory system. It reflects the permanent will of the Government, implemented by the Ministry of Public Health, to strengthen the Cameroonian health system.

We sincerely acknowledge all the people and partners who contributed in any form to the development of this first edition of the National Laboratory Policy in Cameroon.

In particular, our thanks go to:

- the World Health Organization;
- the African Centers for Disease Control and Prevention with the support of SAVEDLIVES and the Fleming Fund;
- CDC Cameroon through the US President's Emergency Plan for AIDS Relief (PEPFAR);
- Global Health Systems Solutions.



# ACRONYMS AND ABBREVIATIONS

<b>AMR</b>	Antimicrobial Resistance
<b>ASLM</b>	African Society for Laboratory Medicine
<b>ATLAS</b>	Assessment Tool for Laboratory Services and Supply Chain
<b>CAFETP</b>	Cameroon Field Epidemiology Training Program
<b>CAMELS</b>	Cameroon Association for Medical Laboratory Science
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CHO/NECC</b>	Catholic Health Organization/National Episcopal Conference of Cameroon
<b>CIRCB</b>	Chantal Biya International Reference Centre for research on HIV/AIDS prevention and care
<b>CNMC</b>	Cameroon National Medical Council
<b>CPC</b>	Centre Pasteur of Cameroon
<b>CRESAR</b>	Army Health Research Centre
<b>CSCB</b>	Cameroonian Society of Clinical Biology
<b>CTG</b>	Central Technical Group
<b>DAJC</b>	Legal Affairs and Litigation Division
<b>DCOOP</b>	Cooperation Division
<b>DHIS2</b>	District Health Information Software 2
<b>DLMEP</b>	Department for the control of Diseases, Epidemics and Pandemics
<b>DOSTS</b>	Department of Health Care Organization and Technology
<b>DPML</b>	Department of Pharmacy, Drugs and Laboratories
<b>DROS</b>	Division of Operational Research in Health
<b>EQA</b>	External Quality Assessment
<b>FMBS</b>	Faculty of Medicine and Biomedical Sciences
<b>GHSS</b>	Global Health Systems Solutions
<b>GPHC</b>	General Population and Housing Census
<b>GVFI</b>	Global Viral Forecasting Initiative
<b>HD</b>	Health District
<b>HF</b>	Health Facility
<b>HGOPED</b>	Douala Gyneco-Obstetrics and Pediatric Hospital
<b>HIV</b>	Human Immunodeficiency Virus
<b>HSS</b>	Health Sector Strategy
<b>IDSR</b>	Integrated Disease Surveillance and Response
<b>IGSPL</b>	General Inspectorate of Pharmaceutical Services and Laboratories
<b>ISO</b>	International Standardization Organization
<b>LANADA</b>	National Laboratory for the Analysis of Foodstuffs
<b>LANAVET</b>	National Veterinary Laboratory
<b>LIS</b>	Laboratory Information System
<b>LNAD</b>	National Laboratory for the Diagnostic Analysis of Agricultural Products and Inputs
<b>MINADER</b>	Ministry of Agriculture and Rural Development
<b>MINDEF</b>	Ministry of Defense
<b>MINEPAT</b>	Ministry of Economy, Planning and Land Planning
<b>MINEPDED</b>	Ministry of the Environment, Nature Protection and Sustainable Development
<b>MINEPIA</b>	Ministry of Livestock, Fisheries and Animal Industries
<b>MINESUP</b>	Ministry of Higher Education
<b>MOH</b>	Ministry of Public Health
<b>NACC</b>	National AIDS Control Committee
<b>NDS30</b>	National Development Strategy 2020-2030
<b>NEIDRL</b>	National Early Infant Diagnosis Reference Laboratory
<b>NIS</b>	National Institute of Statistics
<b>NLP</b>	National Laboratory Policy

<b>NMCP</b>	National Malaria Control Programme
<b>NPHL</b>	National Public Health Laboratory
<b>NPHO</b>	National Public Health Observatory
<b>NPSC</b>	National Pharmaceutical Society of Cameroon
<b>NSIF</b>	National Social Insurance Fund
<b>NTBCP</b>	National Tuberculosis Control Programme
<b>ONPMS</b>	National Order of Medico-Sanitary Professions
<b>QMS</b>	Quality Management System
<b>RDPH</b>	Regional Delegation of Public Health
<b>RENALAB</b>	National Network of Laboratories
<b>RH</b>	Regional Hospital
<b>TBRL</b>	Tuberculosis Reference Laboratory
<b>UB</b>	University of Buea
<b>UD</b>	University of Douala
<b>UTH</b>	University Teaching Hospital
<b>UYI</b>	University of Yaounde I
<b>WHO</b>	World Health Organization



# DEFINITION OF TERMS

**Accreditation:** procedure whereby an authoritative body provides formal recognition that an organization is competent to perform specific tasks [1].

**Biosafety:** set of measures aimed at preventing and countering the dangers associated with the handling and use of biological materials in diagnostic, teaching, industrial and research laboratories [2].

**Biosecurity:** set of principles, technologies and operational practices related to containment that are applied to prevent deliberate exposure to pathogens or toxins. Biosecurity therefore refers to security measures aimed at preventing the loss, theft, misuse, diversion and intentional release of infectious materials or toxins [2].

**Certification:** procedure whereby a third party gives written assurance that a product, process or service complies with the requirements specified by a qualified and independent body tending to attest a product/service [1].

**Medical Laboratory:** laboratory intended to carry out biological, microbiological, immunological, biochemical, immuno-hematological, hematological, biophysical, cytological, anatomopathological, genetic tests or other tests of substances of human origin to provide useful information for the diagnosis, management, prevention or treatment of disease or the assessment of the state of health of human beings, and which can offer advice covering all aspects of laboratory examinations, including the interpretation of results and advice on other appropriate complementary examinations [1].

**Standard:** document established by consensus and approved by a recognized organization, which provides for common and repeated use of rules, guidelines, or characteristics, for activities or their results guaranteeing an optimal level of order in a given context [3].

**National laboratory network:** platform for permanent collaboration between public and private medical laboratories operating according to specific principles and procedures.

**Quality management system:** management system to guide and control an organization in terms of quality. The term "quality management system" mentioned in this definition refers to the general management activities, the provision and management of resources, the pre-analytical, analytical and post-analytical processes, as well as evaluation and continuous improvement [1].

**One Health:** The One Health approach applies to the design and implementation of programmes, policies, legislation and research where multiple sectors communicate and collaborate to improve public health outcomes [4].



# I. BACKGROUND AND RATIONALE

## I.1. Geographical Situation

The Republic of Cameroon is a Central African country located at the bottom of the Gulf of Guinea, between the 2nd and 13th degrees of the North latitude and the 9th and 16th degrees of the East longitude. Its area is estimated at 475,650 km<sup>2</sup>. The country has about 590 km of coastline along the Atlantic Ocean coast and 4,591 km of land borders: with Nigeria to the west (1,690 km), Chad to the northeast (1,094 km), the Central African Republic to the East (797 km), Congo (523 km), Gabon and Equatorial Guinea (189 km) to the South [5].

## I.2. Political and administrative organization

The constitutional provisions in place since January 18, 1996 make Cameroon a decentralized unitary State. A multicultural and multilingual State with more than 300 ethnolinguistic groups living in the country, Cameroon has adopted french and english as official languages of equal value. The principle of separation of powers is enshrined in the country with the establishment of three main powers, namely the executive, the legislative and the judicial.

Administratively, the country is composed of 10 regions subdivided into 58 departments, 360 sub-divisions, 360 municipalities and 10 regional councils and councils. The system of decentralization now provides for the transfer of competencies and resources to decentralized territorial authorities [5].

## I.3. Macroeconomic situation

In 2020, the Gross Domestic Product (GDP) of Cameroon was estimated at FCFA 922,5 billion with an annual growth rate of 3.5% and an inflation rate of 2.5% [6].

Table 1 : Macro-economic indicators

GDP per capita (FCFA)	922,5
Human Development Index/Rank (2019)	0,563/153
GDP growth rate (2020) (Estimation)	3,5%
Capital expenditure in billions of FCFA (2021 budget)	1 132,9
Investment expenditure in billions of FCFA (2021 budget)	1 132,7
Total budgetary resources in billions of FCFA (2021 budget)	5 131,5
Percentage of budget allocated to Health (2021)	3,8%

Sources : TOFE, December 2021, Finances Law2021

## I.4. Demographic situation

According to the projections of the third General Population and Housing Census (GPHC) in 2020, the population of Cameroon is estimated at 24,910,305 inhabitants, 26,058,314 inhabitants in 2022 and projected at 27,538,142 inhabitants in 2025[7]. This population has been growing at an average rate of 2.4% since 2005 and an urbanization rate of over 52%. At this rate, Cameroon's population is expected to reach 33 million by 2035. More than half of the population (53.2%) lives in urban areas. The cities of Douala and Yaoundé alone account for nearly 20% of the total population. The regions with the highest demographic weight are the Center (19.6%), Far North (18%), Littoral (15.2%) and North (11%). Cameroon's population is essentially made up of young people, with 43.6% under the age of 15; those aged 15 to 34 make up more than 35% of the total population, and those over 60 represent less than 6%. The dependency ratio remains high (85%), resulting in strong pressure on infrastructure and basic social services such as education, health, access to energy and drinking water, food security and land tenure. In 2014, at least 8,088,876 Cameroonians (37.05%) lived below the monetary poverty line of 931 FCFA per day per adult equivalent to meet basic needs, namely food and non-food needs. Poverty is most prevalent in rural areas (about 90%) and in the northern regions (over 52%) [8].

Table 2 : Socio-demographic indicators

Total estimated population in 2022	26 058 314
0 -14 years	43,6%
15 - 64 years	64,2%
65 and above	53,5%
Population aged 0 to 24 years	2,7%
Population aged 25 years and above	37,6%
Average population growth rate	2,6%
Population density per Km <sup>2</sup>	48 hbts /Km <sup>2</sup>
Population distribution (Urban/Rural)	52%
Poverty rate	37,5% in 2014
Broad unemployment rate	5,7%
Overall underemployment rate	71%
Life expectancy at birth	59 ans

Sources : Central Bureau of the Census and Population Studies, 3rd GPHC

### I.5. Humanitarian and security situations

The conflict and terrorism situation observed in northern Nigeria and the Central African Republic (CAR) has an impact on the security of people and property in the Far North, Adamawa and East Regions, thus hindering the provision of basic social services (health services and care). The number of refugees from these two countries was estimated at 246,000 in 2019. In addition, these conflicts have led to the internal displacement of 665,000 people in Cameroon [9].

Insecurity increases the level of health vulnerability of the population and animals, creating additional needs for health services and care, and requiring a higher level of health supervision.

### I.6. Communication channels

Cameroon has a diversified transport network that includes roads, railways, seaports and airports. The road network has developed considerably, reaching 121 501 km in 2020, of which only 7252 km were

tarred [10]. This poorly maintained network limits the movement of people and goods and hinders access to various services. Concerning access and use of Information and Communication Technologies (ICTs), a study carried out in 2014 showed that 78.9% of Cameroonians used a mobile phone, 8.3% a fixed telephone, 21.2% a computer and 16.2% internet. The mobile phone has thus become the most widely used communication tool by the population with a penetration rate growing at an exponential rate and geographical coverage of 83.3%. However, exposure to Information and Communication Technologies remains low. Consequently, health information is not always accessible.

### I.7. Public health system in Cameroon

The health sector in Cameroon is structured in three levels forming a pyramid whose functional relationships are shown in the table below. It has three sub-sectors: a public sub-sector, a private sub-sector and a traditional sub-sector [5].

**Table 3:** organization of the health system; sources: Health Sector Strategy 2016-2027

Level	Administratives Structures	Competences	Health Structures	Dialogue Structures
<b>Central</b>	Minister's office, Secretariat General, Departments and similar s structures	- Development of concepts, policies and strategies ;  - Coordination  - Regulation	General Hospital, University Teaching Hospitals, Central Hospitals and others ranking as such CENAME,CPC, CHRACERH, LANACOME,CIRCB.ONSP	National Council for Health Hygiene and Social Affairs
<b>Intermediate</b>	10 Regionals Delegations	Technical support to health districts	Regional Hospitals and others ranking as such, Regional Drug Supply Centres	Regional Fund for Health Promotion
<b>Périphérique</b>	189 Health Districts	implementation of programmes	-District Hospitals  - Clinics ;  - SDHCs ;  -HCs, Healthcare practice	DHC ; DMC  HC ; MC

In July 2022, Cameroon has 189 health districts divided into 1,462 health areas which are composed of 4,055 public and private health facilities. In the public sector, there are five (5) General Hospitals, five (5) Central Hospitals, eight (8) Regional Hospitals, sixteen (16) Regional Hospitals, one hundred and sixty-five (165) District Hospitals, two hundred and fifty-five (255) Medical Health Centers and 2,229 Integrated Health Centers.

In addition, there are specialized Treatment Centers for Tuberculosis (CTT) and specialized units for the treatment of people living with HIV/AIDS, including care units (UPEC) in district hospitals and approved treatment centers (CTA).

Among the public health facilities, there are also military health facilities and a research laboratory for the health of the armed forces (CRESAR). The Ministry of Justice also has laboratories in penitentiary centers. The military health centers are coordinated by the Directorate of Military Health of the Ministry of Defense (MINDEF)

**Table 3 :** Health and demographic indicators

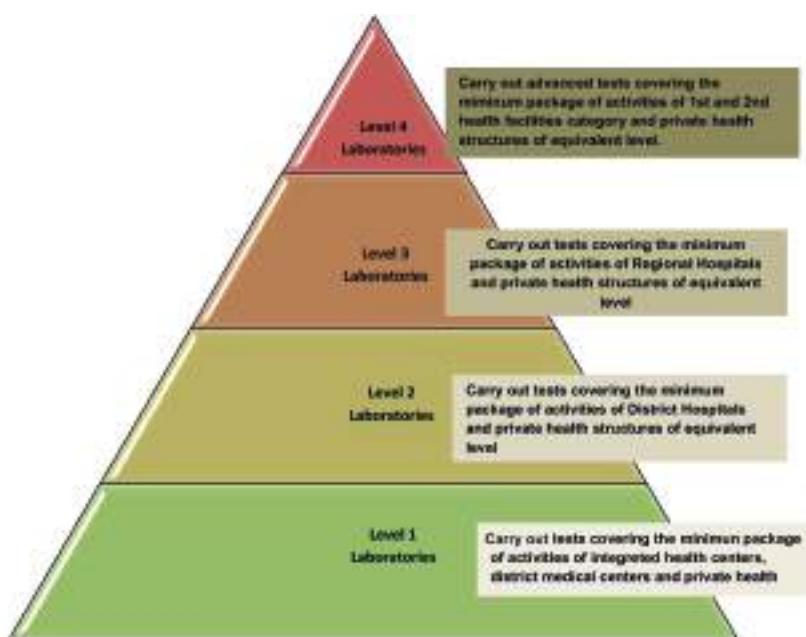
Confirmed cases of patients contaminated with COVID-19 (MOH, 29/05/2021)	78 929
COVID-19 related deaths (29/05/2021)	1 275
Remissions of COVID-19 patients (MOH, 29/05/2021)	73 974
COVID-19 active cases (MOH, 29/05/2021)	3 680
Prevalence of hypertension (2020)	20%
Unmet need for family planning	34,30%
Under-5 mortality rate (2019)	75‰
Maternal Mortality Rate (Deaths per 100,000 live births), 2011	782
HIV prevalence (DHS 2018)	2,7%
Access to improved toilets (Households) (INS 2020)	61%
Vaccination coverage, all vaccines (2018)	52%
Vaccination coverage, measles (2018)	65%
Stunting rate in children under 5 years of age (2018)	27%
Life expectancy at birth (2015)	58,6 (F) & 55,9 (M)
Child mortality rate at birth per 1,000 live births (MOH & NIS 2018)	48‰
Under-5 mortality rate per 1,000 live births (MOH & NIS 2018)	80‰

Sources : NIS 2020, NACC 2020, WBG 2019, NTCP 2020, NMCP 2020

The medical laboratories are organized into four levels according to :

- the minimum package of activities performed ;
- human resources ;
- infrastructure and equipment.

The figure below presents this organization in levels:



**Figure 1:** Classification of laboratories in Cameroon

### I.8. Laboratories in the Cameroonian Health System

Laboratories play a key role in the health system. In Cameroon, laboratory activities are carried out in the human, animal, plant and environmental health sectors. This leads to collaboration between the Ministry of Public Health and other Ministries to reinforce the quality of care and fight against epidemics, pandemics, epizootics and major plagues.

Laboratory activities contribute primarily to the diagnosis of pathologies, epidemiological surveillance and, consequently, research. In this context, mastering practices and techniques of laboratory organization and operation are essential conditions for success. However, these activities are carried out at all levels of the health pyramid in a disparate manner with no real organization, standardization or coordination.

Taking into account the requirements of the WHO Regional Committee for Africa, which recommends to Member States to **"develop and strengthen comprehensive national laboratory policies, and draw up plans to adequately equip and staff National Laboratories"**, several initiatives and actions have been carried out by the Ministry of Public Health in collaboration with other ministries and with the support of development partners to tackle the various issues [11]. These include the development of legislative and regulatory instruments and other normative documents, the training of personnel, the provision of equipment, the gradual establishment of a laboratory quality assurance system which will accompany laboratories for accreditation and the creation of a multi-disciplinary working group to develop this document.

This National Laboratory Policy, which is the result of a series of consultations involving several national and international experts, reviews the current situation of the various components of the analytical testing laboratories in Cameroon by identifying the problems that hinder the development of this field. It also sets out strategic orientations aimed at guaranteeing better access to quality laboratory services for the entire population.

## II. METHOD AND PROCESS OF ELABORATING THE NATIONAL LABORATORY POLICY

The National Laboratory Policy document is the result of a long process that comes from the following:

- the 2014 situation analysis of laboratories;
- an overview of the quality assurance of 2021;
- the assessment of the laboratory system in 2019 and 2022.

This methodological note reveals the process and working tools used in drafting this document. It drew inspiration from several reference documents, namely:

- the National Development Strategy 2020-2030;
- the Health Sector Strategy (HSS, 2016-2027);
- the WHO guide for the development of a national health policy;
- the WHO guide for the development of peripheral and district laboratory services to support universal health coverage;
- the Africa CDC/Africa Union Guidance for Establishing a National Laboratory Quality Framework, First Edition 2021.

The methodology is structured around the following points:

- the organizational framework;
- the involvement and participation of all stakeholders in the process;
- major steps and process.

### **Organizational framework**

On the organizational level, a working group composed of staff from the DPML, NPHL, WHO, and CDC was set up. This group had the mission to design a national policy and a Strategic Plan for Laboratory Development.

### **Stakeholder involvement and participation**

The development of the National Laboratory Policy was largely participatory and consultative. Efforts were made to involve participants from the public and private sectors and technical and financial partners including those from partner ministries as part of the "One Health" approach.

To achieve the objectives, several methods were used: document reviews, data collection with the ATLAS tool on about 750 laboratories at all levels, tabulation and analysis of the data collected, evaluation of the national laboratory system with the LABNET evaluation grid of ASLM; workshops

the LABNET evaluation grid of ASLM; workshops and participatory consultations. These methods enabled an analysis of the situation and a better understanding of the needs.

### **Major steps and process**

The process of developing the NLP was based on the following major steps:

- a situation analysis of laboratories in Cameroon;
- the formulation of policy orientations;
- the development of the implementation framework.

The situation analysis of laboratories was done through the assessment of data collected from a representative sample of laboratories in Cameroon, the description of the institutional situation of the laboratory services and the establishment of the diagnosis of the national laboratory system through the problems identified.

The formulation of policy orientations was derived from the weaknesses identified in the laboratory system. Several workshops with stakeholders and consultations with experts provided to the country by the Technical and Financial Partners helped to fine-tune this chapter.

The process ended with the development of the implementation and monitoring/evaluation framework for this policy.



### III. SITUATION ANALYSIS

As a prelude to the development of the National Laboratory Policy, a situation analysis of the national laboratory system was conducted through an inclusive and multi-sector process. At the end of this analysis, observations were made in the different sectors, helping to identify the strengths, weaknesses, opportunities and threats of our laboratory system in each of the following areas:

- legal and institutional framework;
- structural organisation of laboratories;
- human resources;
- infrastructure;
- equipment, reagents and consumables;
- quality management;
- biosafety and biosecurity;
- laboratory information system;
- funding;
- research and cooperation;
- public health surveillance;
- multi-sector collaboration;
- monitoring and evaluation.

#### III.1. Legal and institutional framework

In Cameroon, activities related to laboratories are governed by legal instruments made up of laws, decrees, orders and decisions listed in the appendix. The analysis of these tools mainly reveals the existence of legal vacuums and many obsolete instruments, which prevent better supervision of laboratory activities in Cameroon.

At the institutional level, several bodies are in charge of the implementation and regulation of the laboratory policy. The Presidential Decree No. 2013/093 of 3 April 2013 to organise the Ministry of Public Health creates a Sub-Department of Laboratories and Blood Transfusion within the Department of Pharmacy, Drugs and Laboratories. However, this structure, which is responsible for organising the national laboratory system, does not have sufficient autonomy to carry out its missions.

Furthermore, Order No. 2964/MINSANTE of 9 October 2013, on the creation, organisation and functioning of the National Public Health Laboratory (NPHL) places this structure under the coordination of the DPML. However, this legal instrument does not allow the Laboratory to optimally fulfil the missions that are incumbent on a Public Health Laboratory.

The Inspectorate General for Pharmaceutical and Laboratory Services (IGSPL), whose role is to supervise laboratories, is not always able to perform its missions due to the insufficiency of normative and regulatory texts and documents.

#### III.2. Structural organisation

In Cameroon, the national laboratory system is organised in the public and private sectors. Thus, a distinction is made between laboratories housed in public or private health facilities, autonomous laboratories and research centres. In the public sector, the laboratories in health facilities (HFs) are organised according to the health pyramid. Although there is an instrument specifying the content of the minimum package for laboratory activities, it does not take into account all the categories of health facilities. In the private sector, laboratories with an adequate and sometimes advanced technical platform are generally concentrated in large cities. Generally, there are:

- the inadequate distribution of laboratories on the national territory;
- the absence of an instrument categorising laboratories by level;
- a proliferation of unauthorised laboratories;
- bad practices that do not comply with professional ethics.

#### III.3. Training and human resources

##### Initial training

Laboratory staffs are trained in public and private training schools. Entry into these training schools is usually through competitive examinations. These include:

- clinical biologists, holders of a Doctorate Degree in Medicine or Pharmacy and, specialized in clinical biology obtained from a national or foreign Faculty of medicine or pharmacy. Only the Faculty of Medicine and Biomedical Sciences of Yaoundé I University offers this specialization in Cameroon;
- medical and health engineers with a diploma in biomedical engineering who are trained in five years in training schools at national level or abroad;
- lab technicians (specialized in medical biology) trained for three years in public and private training schools in the country;
- assistant lab technician (ATMS).



There are also courses in clinical biology and other fields of biology in universities or private professional institutes for the award of degrees in accordance with the Licence, Master and Doctorat curriculum. Several other diplomas are also listed from institutions or schools in foreign countries. The most common are:

- the Fellow degree obtained in Nigerian training schools;
- the Associates of the Institute of Medical Laboratory Technology (AIMLT);
- Medical laboratory Officer Diploma;
- CES (Certificate of Specialized Studies).

### **Continuous training**

Some continuous training is offered by partners in quality assurance, quality management, biosecurity, biosafety, and analytical techniques of some diseases. However, the training curricula are not harmonised. Overall, a standardised continuous training programme for laboratory staff has not been put in place by the ministry.

Laboratory staff are trained in public and private academic and professional institutions. A field epidemiology training programme (CAFETP) has been implemented at different levels (advanced, intermediate and basic). However, the advanced level of this programme no longer takes into account laboratory and pharmacy health professionals.

### **Human resources**

In public health facilities, there is an inequitable distribution of human resources that varies from one facility to another. The situation analysis of laboratories carried out in 2014 in 756 laboratories shows a deficit in the presence of laboratory staff profiles at different levels. More specifically, it shows a deficit of 70% and 49% respectively in Laboratory Technicians and Health Technicians of laboratories of IHCs and MHCs, 86% for laboratory engineer in DHs, and 94% for biologists in CHs and RHs [12].

Furthermore, the absence of an organisation bringing together all the professionals working in the biology field hinders the development of an exhaustive database of laboratory staff. The main shortcomings relating to training and human resources are:

- the non-harmonisation of laboratory staff profiles;
- the non-harmonisation of training curricula;
- the absence of a continuous training plan for laboratory staff;
- the absence of standards for laboratory personnel;
- the absence of a licensing mechanism for laboratory

personnel;

- the absence of a career profile for laboratory staff;
- the absence of a comprehensive staff recruitment strategy for public laboratories;
- the lack of bioinformaticians.

### **III.4. Infrastructure**

Majority of laboratory premises in both the public and private sectors do not meet established standards because they are not specifically built for this purpose. Thus, it was noted that apart from general and regional hospitals and specialised hospital centres, most laboratories in health facilities do not meet the standards in terms of space. It should also be noted that some laboratories do not have alternative sources of electrical energy for the continuous operation of services.

### **III.5. Equipment, reagents and consumables**

#### **III.5.1. Equipment**

According to the situation analysis of laboratories carried out in 2014, there is a heterogeneity of brands and technologies of laboratory equipment. There are approximately 10 different models per speciality, reflecting the lack of harmonisation of laboratory equipment per level. The results of the evaluation of laboratories and their supply chain carried out in 2014, reveal the situation of functional equipment per speciality. Thus, there is 50% for biochemistry automatons, 21% for CD4 and 33% for haematology automatons, to name but a few, with a maintenance rate of 69%, 80% and 60% respectively.

The analysis of these data reveals:

- the absence of a maintenance and monitoring plan for the equipment;
- the absence of signed maintenance contracts for most of the equipment;
- recurrent service interruptions due to numerous breakdowns;
- difficulties in acquiring spare parts;
- the lack of consultation between actors and partners during the selection and acquisition of certain equipment has led to the heterogeneity of brands on the field.

#### **III.5.2. Reagents and consumables**

Despite the requirement of approval procedures, most of the reagents and medical devices used do not have a Marketing Authorisation (MA), which does not guarantee the quality and reliability of analysis results. The lack of stock management sometimes leads to stock-outs of essential reagents

and consumables. The various analyses revealed the following:

- the circuit and procedures for supplying reagents, medical devices and other laboratory equipment are not always respected;
- laboratory professionals are not involved in the procedure for acquiring reagents and consumables;
- a diversity of unapproved reagents are used on the field;
- there is a lack of locally-produced reagents;
- there is not enough post-marketing follow up.

### **III.6. Quality management**

The national quality management strategy for laboratories is under development in Cameroon. Although there is no formal national External Quality Assessment (EQA) programme yet, some laboratories are participating in EQA on an individual basis. To date, six out of seventeen laboratories have been supported towards ISO 15189: 2012 accreditation throughout the country (Bamenda RH, Bamenda TBRL, NEIDRL Mutengene, Buea RH, Limbe RH, CPC Yaounde) and two towards ISO 17025 (CPC Yaounde, LANAVET Garoua) for some tests. However, there is:

- a lack of national quality standards;
- poor deployment of the quality management system in the laboratories of the network;
- lack of awareness and training of laboratory staff on quality.

### **III.7. Biosafety and biosecurity**

A National Laboratory Biosafety and Biosecurity Guide was validated and adopted in July 2019, but its dissemination and implementation are considered insufficient. In addition, there is:

- an absence of standard operating procedures on biosafety and biosecurity;
- lack of control in waste management in laboratories;
- insufficient access to efficient incinerators for most laboratories;
- unvaccinated staff working in laboratories to prevent contamination during work.

### **III.8. Laboratory Information System**

Some laboratories have an information system on physical and/or digital media to capture and transmit their activities data. In the context of COVID-19, information systems have been set up to manage the results of authorised laboratories. Furthermore, 360 laboratories were mapped out in 2019, which facilitates access to information on their service provision.

However, it is noted that:

- the notification and transmission of test results is only done for notifiable diseases;
- most laboratories do not have an internal LIS;
- apart from a few health programmes, the collection, management and archiving of laboratory data are neither systematised nor standardised at the national level (collection and management tools differ from one laboratory to another);
- the laboratory data transmission circuit is not formal;
- Dhis2, which is the main system for data feedback set up by the moh, is not compatible with the information systems of the laboratories on the field;
- research activities are carried out in the laboratories but the results of these remain insufficiently disseminated at the national level.

### **III.9. Funding**

Laboratory activities are mainly financed by the State budget, support from development partners, and private promoters and revenue generated by services through cost recovery. There are also some initiatives to finance research projects hosted by certain laboratories. However, there can be noted:

- the absence of a management framework regarding the resources generated by laboratories housed in health facilities to contribute to their operation and development;
- insufficient coordination of subsidies and financial support from development partners;
- poor regulation of the pricing of biological procedures at all levels of the laboratories; which encourages poor governance practices;
- the revenue obtained from in-house laboratories in the public sector is not mainly reused for their operation.

Generally, resource mobilisation remains insufficient as compared to needs, particularly for the implementation of a quality management system.

### **III.10. Research and Cooperation**

#### **III.10.1. Research**

Several institutions are working in the field of research, generating a large quantity of data. However, there can be noted:

- insufficient exploitation of laboratory data for research purposes;
- low mobilisation of resources for research and poor collaboration between research institutions and laboratories;
- absence of regulations on the creation and operation of bio banks.

### III.10.2. Cooperation

The complementarity approach established between laboratories to improve the quality of care remains embryonic. Although there are inter-institutional conventions and some laboratories receive multiple supports from partners and other international organizations, some difficulties still exist. These are:

- low visibility of existing interventions from partners at all levels;
- poor communication and coordination of laboratory activities;
- an imbalance in the development of laboratory capacity due to the absence of a platform for consultation among stakeholders in the different sectors.

### III.11. Public Health Surveillance

Cameroon adopted an integrated disease surveillance and response strategy that takes into account about 49 priority diseases [13]. However, there is no national surveillance strategic plan and no integrated system for transporting samples to reference laboratories. However, there is a routing system of samples for vaccine-preventable diseases and or samples for diseases in some programmes such as HIV and TB, which is not the case for other diseases.

### III.12. Multi-sector Collaboration

There are a number of laboratories in the human health, animal health, plant health and environmental sectors involved in strengthening the laboratory system. The animal health sector has a National Veterinary Laboratory (LANAVET) created by a presidential decree in 1983, a National Laboratory for the Analysis of Foodstuffs (LANADA), private veterinary laboratories as well as veterinary clinics that carry out some basic analyses as part of their activities. In the area of plant health, there is a National Laboratory for Diagnostic Analysis of Agricultural Products and Inputs (LNAD) and private laboratories with more or less equipped technical platforms. Environmental analyses are carried out in the laboratories of other sectors, including university research laboratories.

Although collaboration among the laboratories of these different sectors involved in the "One Health" approach in case of public health emergencies already exists, data sharing and coordination of routine laboratory surveillance interventions is still a challenge. Despite the lack of formalisation of a national laboratory network, some activities are carried out in a concerted manner among the different sectors. Thus, LANAVET is one of the eight sentinel sites for AMR surveillance in Cameroon. The NPHL collects data from these sites on a monthly basis but feedback is not always effective. A draft joint order creating a network between human, animal, plant and environmental health laboratories is awaiting signature.

### III.13. Monitoring and Evaluation

There are some tools and indicators to monitor laboratory activities for some priority diseases. Supervision of priority diseases is regularly carried out by public health programmes. However:

- the country did not define quality indicators for the monitoring of laboratory activities;
- supervision is still insufficient in all the laboratories;
- feedback from supervision is not always provided.

The table below summarises the main strengths, weaknesses, opportunities and threats identified in the situational analysis of the national laboratory system:



**Table 5:** Strengths, weaknesses, threats and opportunities of the national laboratory system

N	Domains	Strengths	Weaknesses	Threats	Opportunities
1	<b>Institutional, judicial and regulatory framework</b>	Existence of a Sub-Directorate of Laboratories and Blood Transfusion at the Ministry of Public Health Existence of a National Public Health Laboratory Existence of a National Strategic Plan for the development of laboratories Existence of some normative documents Existence of a regulation governing the approval of private laboratories	Lack of a specific Directorate in charge of Laboratories Lack of a national laboratory policy Absence of a Technical Working Group on Laboratories Absence of standards and organisation of laboratories absence of a functional laboratory network		Presence of several partners working to strengthen the laboratory system
2	<b>Structural organisation of laboratories</b>	Existence of laboratories at each level of the health system	Inadequate distribution of laboratories throughout the country Absence of a classification of laboratories lack of standards for laboratory construction Presence of clandestine Laboratories		
3	<b>Training and Human Resources</b>	- Existence of training programmes for laboratory staff - Existence of qualified human resources	Inadequate distribution of qualified personnel. Disparity of diplomas and titles of medical biology professionals. Lack of harmonisation and validation of training curricula. Absence of personnel standards Lack of a strategy for staff retention absence of a system of continuous training and retraining.		Existence of a National Human Resources Observatory
4	<b>Equipements, reagents et consommables</b>	Existence of a specialised Commission in charge of the approval of medical analysis reagents. Existence of a health technology policy document (DOSTS) Existence of a National Supply Centre for Essential Medicines and Medical Consumables (CENAME)	Insufficient coordination of the supply chain and management of input stocks. Lack of guidelines for the validation and verification of new equipment and reagents Lack of a maintenance and monitoring plan for equipment, Diversity of non-approved reagents used by the laboratories; Lack of a local production unit for laboratory reagents Insufficient post-market monitoring.	Reagent shortages leading to service interruption. Circulation of poor quality reagents	The updating of the list of the minimum package of reagents and inputs The strengthening of a pool of biomedical engineers for maintenance and essential follow-up Strengthening of the control of the activity of reagent and input manufacturing and distribution establishments Strengthening CENAME's Storage capacities
5	<b>Quality management and biosecurity</b>	Participation in external quality assessment programmes by some laboratories 6 laboratories accredited to ISO 1518:2012 and 2 to ISO 17025 Staff trained in QMS Existence of a national guide on biosafety and biosecurity in laboratories	Lack of national quality standards/referentials Poor deployment of the quality management system Insufficient awareness and training of laboratory staff on quality Lack of SOP on biosafety		Existence of a bilateral and multilateral partnership Support from partners in training personnel capable of leading laboratories towards accreditation.
6	<b>Information and logistics management</b>	Presence of a data reporting system (DHIS2) existence of a circuit for the transmission of surveillance data information system present in some laboratories	Lack of a national computerized system for collecting laboratory data Lack of a laboratory database		

7	<b>Monitoring and evaluation coordination framework</b>	A team of trained inspectors and auditors/mentors in place to monitor and supervise the laboratories existence of some supervision tools existence of some indicators for monitoring laboratory activities for certain priority diseases	Insufficient resources to fulfil supervision and coordination tasks Irregular supervision of laboratories lack of quality indicators Insufficient communication and coordination of laboratory activities		
8	<b>Financing</b>	Laboratory activities financed by the state budget and TFPs There are some projects that finance laboratory activities	Insufficient coordination of subsidies and financial support from TFPs Poor regulation of the pricing of medical biology procedure		
9	<b>Research et cooperation</b>	Presence of several laboratories involved in research Existence of inter-institutional agreements	Insufficient exploitation of laboratory data for research purposes Poor mobilisation of resources for research Low visibility of partners' interventions Lack of a platform for dialogue between actors from different sectors		
10	<b>Multi-sector Collaboration</b>	Collaboration with the animal, plant and environmental sectors in line with the One Health approach Presence of a National Veterinary Laboratory and a National Laboratory for Food Analysis Existence of a National Laboratory for Diagnostic Analysis of Agricultural Products and Inputs	Lack of formalisation of the text establishing and organising the national laboratory network		

## IV. VISION

Provide Cameroon with an efficient laboratory system that can guarantee universal access to quality laboratory services by 2030.

## V. FOUNDATIONS, VALUES AND PRINCIPLES OF THE NATIONAL LABORATORY POLICY

### V.1 Foundations

**At the international level**, this policy is in line with the international commitments ratified by the Government:

- the Maputo Declaration of 24 January 2008 on the harmonisation and standardisation of clinical laboratory equipment and tests;
- the Resolution AFR/RC58 of June 2008 of the WHO African Regional Committee on the challenges to be met in strengthening laboratories in Africa ;
- the International Health Regulations adopted in 2005 and entered into force on 15 June 2007;
- the 2015 Sustainable Development Goals (SDGs): Goal 3 is specifically related to health. This goal targets the reduction of maternal and child mortality, the end of epidemics related to major communicable diseases and the reduction of premature mortality related to non-communicable diseases, through universal access to health care and services.

**At the national level**, this policy document contributes in achieving the objectives of:

- the National Development Strategy 2020-2030;
- the 2016-2027 Health Sector Strategy;
- the 2016-2020 National Health Development Plan

adopted in 2016, whose general objective is to improve the health status and well-being of the population ;

- the integration of laboratory services into the health map.

### V.2. Values

This policy is based on the following values:

- **the right to quality laboratory services:** all people should have access to quality laboratory services
- **equity in the distribution of laboratory services:** all people should have access to laboratory services regardless of age, gender or social status;
- **ethics:** respect for patients' rights (confidentiality, non-discrimination, non-stigmatisation, integrity, etc.)
- **quality:** reliability of processes and results.

### V.3. Principles

This policy is based on the following principles:

- **decentralisation of laboratory services:** access to laboratory services everywhere in the country;
- **quality of services:** the services provided by the laboratories shall comply with national and international norms and standards;

- **good governance:** accountability, transparency and social control shall be strengthened for better participation and coordination of stakeholders at all levels working to achieve the objectives of the NLP.

- **one Health Approach:** shall involve laboratories of other sectors in the achievement of public health missions.

## VI. GOAL AND OBJECTIVE

### VI.1. Goal:

This National Laboratory Policy aims at improving healthcare of the population through quality laboratory services.

### VI.2. General Objective

The objective of this policy is to strengthen the laboratory system in Cameroon.

### VI.3. Strategic Orientations

From the situational analysis carried out, the following strategic orientations were identified:

- strengthening the legal and institutional framework;

- strengthening the operational capacity of laboratories;
- improving the quality management in laboratories;
- strengthening biosafety and biosecurity;
- strengthening the laboratory information system;
- improving the financing of laboratory activities
- improving the research and cooperation framework
- improving the framework for monitoring and evaluation of laboratory activities.

## VII. POLITICAL DECLARATION

### V.1. Strengthening the legal and institutional framework

Legislation and regulations relating to laboratory activities must be in line with the National Laboratory Policy (NLP) and international standards in order to ensure better regulation of the opening and operation of laboratories, initial and continuous training of laboratory personnel, discipline in the practice of medical biology and the upkeep of laboratory standards [14].

Legislation and regulations concerning laboratory services should be harmonised with the national laboratory quality policy, the laboratory strategic plan, and comply with international recommendations [15]. For this purpose, the legal framework for the laboratory network should be improved through:

- strengthening the instruments defining the modalities of practice in the field of biology as well as those relating to the modalities of authorising the opening and operation of laboratories;
- the development of regulations on laboratory accreditation and certification;
- the strengthening of regulations on the pricing of biological acts;
- the development of regulations relating to metrology;
- the development of standards relating to infrastructure, materials and equipment, and human resources for laboratories.

At the institutional level, it is important to make efforts to create strong institutions capable of improving the coordination and regulation of laboratory activities in all sectors and at all levels of the health pyramid. In this regard, actions should be taken to:

- create a department dedicated to the regulation of laboratory activities;
- Put in place a multi-sector surveillance network for antimicrobial resistance in accordance with the one health approach;
- designate a body in charge of laboratory accreditation and certification which will have to comply with the requirements of ISO 17011 (conformity assessment requirements for accreditation bodies carrying out conformity assessment);
- develop incentive measures to encourage laboratories to engage in continuous quality improvement by using laboratory certification and accreditation processes;
- encourage reference laboratories to become accredited to international standards (ISO 15189 or ISO 17025);
- encourage network laboratories to implement national quality standards;
- encourage institutions offering maintenance and calibration services for laboratory equipment to be accredited to ISO 17025 in order to guarantee the quality of these services;

- strengthen coordination mechanisms for laboratory services at all levels between the Government and partners;
- strengthen accountability and good governance in the management of laboratory resources;
- establish an ISO 17025 accredited National Metrology Institute to ensure appropriate competence in the maintenance and calibration of laboratory equipment;
- put in place a coordination mechanism to ensure rational and efficient use of financial resources provided by development partners in accordance with national policy and the laboratory strategic plan.

## **VII.2. Strengthening the operational capacity of laboratories**

### **VII.2.1. Structural organisation**

In order to improve the coordination and management of laboratory activities at all levels of the national laboratory network, a coherent organisational structure and an autonomous laboratory authority must be put in place. The sector departments in charge of laboratories will ensure the administrative and technical supervision of laboratory activities of all public and private sector facilities and facilitate and improve service delivery at all levels of laboratories in the various sectors.

For a coherent and functional structural organisation of laboratory activities, the following measures should be put in place:

- the categorisation and organisation of laboratories per class or level;
- the development of a functioning national laboratory network;
- the development and regular updating of a national mapping of laboratories;
- strengthening the operational capacities of the laboratory network coordination platform;
- the development of the increase in the provision of laboratory services throughout the country;
- strengthening the organisational and structural capacities of the various Laboratory Regulatory Authorities in the different sectors;
- strengthening collaboration with the national body in charge of standardisation.

### **VII.2.2. Training and Human Resources**

The provision of quality health services requires a sufficient number of qualified personnel in each laboratory. To achieve this, the personnel must have the skills to enable the laboratories to comply with national and international standards in this area. Periodic evaluation of these skills will ensure continuity

in the quality of the services provided. Efforts to ensure the permanent availability of well-trained, competent and motivated laboratory personnel capable of providing quality laboratory services shall include:

#### **VII.2.2.1. Training**

- update and harmonise the curricula for the initial and continuing training of laboratory personnel, in collaboration with the administrations concerned ;
- include continuing training as a requirement in the process of evaluation of competences and certification of laboratory personnel;
- include quality management in the curricula for initial and continuing training of professionals in the laboratory sector;
- develop a mentoring system for laboratories.

#### **VII.2.2.2. Human resources**

- develop sensitisation programmes on the importance of quality, compliance with standards and the implementation of national guidelines for laboratory personnel, managers and other stakeholders;
- promote ethics in carrying out laboratory activities;
- develop and continuously update the mapping of laboratory personnel in the public and private sectors;
- develop a career and retention plan for laboratory personnel
- organise the practice of the medical biology profession;
- obligation for laboratories to have a qualified laboratory director, quality manager and biosafety manager.
- determine and continuously update the ratio between the staff and the workload of each laboratory.

#### **VII.2.3. Infrastructure**

Each laboratory must have adequate infrastructure to ensure an effective and efficient service. Therefore, every laboratory should be designed in such a way that there is enough space to carry out the activity package corresponding to its level, the installation and storage of equipment, the safety of personnel and clients. In order to ensure the construction and maintenance of laboratory infrastructure in accordance with the relevant norms and standards, action will be taken to:

- develop the standards relating to the laboratory infrastructure according to the package of activities carried out or the level in the health pyramid;
- improve quality of laboratory infrastructure at all levels of the health pyramid;

- develop a contingency plan to ensure a continuous supply of energy resources for the continuity of service in each laboratory.

## **VII.2.4. Equipment, reagents and consumables**

### **VII.2.4.1 Equipment**

In order to guarantee quality results, all laboratories must be equipped with materials and equipment adapted to the analyses carried out according to their level and sector. The policy on equipment shall consist, as a matter of priority, of the implementation of the following actions:

- the development of standards relating to laboratory equipment according to the package of activities carried out or the level to which they belong in the health pyramid;
- the strengthening of the modalities of selection, acquisition and installation of laboratory equipment adapted to the different categories, taking into account the environmental risks;
- the strengthening of equipment maintenance, calibration and services at all levels according to the standards in force;
- promoting the use of common equipment for each laboratory service package;
- strengthening metrological control and maintenance procedures for laboratory equipment.



### **VII.2.4.2 Reagents and consumables**

An efficient system for the management of laboratory reagent and consumable supplies must be put in place in order to ensure accessibility and permanent availability of quality reagents and consumables in both the public and private sectors. In this regard, actions to be taken shall include, among others, the following:

- strengthening the system of approval and supply of laboratory reagents and consumables;
- strengthening the control of the supply circuit and the quality of reagents (including reactovigilance) and laboratory consumables;
- updating and monitoring the application of national guidelines and procedure for selection, acquisition, distribution and stock management;
- promoting local production of quality reagents and consumables in collaboration with pharmaceutical industries, universities, research centres and partners.

## **VII.3. Improving the quality management in laboratories**

### **VII.3.1. Quality**

The cost of poor quality is greater than the investment made in setting up a quality management system in the laboratory. It is therefore necessary to implement quality management systems (QMS) in all laboratories in order to guarantee the quality of the biological analyses performed and consequently improve the health care provided to patients. Actions that will be undertaken to ensure the quality of laboratory services in accordance with the relevant standards will focus on:

- developing laboratory quality standards in the network;
- establishing a quality management system in all laboratories;
- deploying a culture of quality in all laboratories;
- developing a national external quality assessment (EQA) programme;
- encouraging reference laboratories to participate in international external quality assessment programmes;
- developing mechanisms for the certification of laboratory professionals;
- promoting the establishment of an independent laboratory certification/accreditation body or becoming a member of an existing body;
- strengthening laboratory monitoring and inspection;
- establishing a mechanism for laboratory accreditation and certification.



### VII.3.2. Public health surveillance

The capacity of laboratories should be strengthened in the organisation, management and coordination of epidemiological surveillance according to the One Health approach. For this purpose, the following measures shall be taken:

- developing a national network of laboratories;
- improving the reference system for biological samples;
- developing biobanks;
- strengthening the system of surveillance, preparedness and response to epidemics;
- improving the antimicrobial resistance (AMR) surveillance system.

### VII.4. Strengthening biosafety and biosecurity

All necessary steps shall be taken to comply with regulatory obligations and standards relating to the protection of personnel, the environment and adherence to safety and security protocols by laboratory personnel. For this purpose, the following measures shall be put in place:

- developing biosafety and biosecurity guidelines;
- monitoring the implementation of national; biosafety and biosecurity guidelines
- setting up a functional laboratory waste management system in accordance with national guidelines in this area;
- strengthening infrastructure, equipment and capacity of laboratory personnel to ensure compliance with biosafety and biosecurity in laboratories;
- putting in place a secure and standardised system for the collection, storage and transport of samples.

### VII.5. Strengthening the Laboratory Information System (LIS)

Laboratory services should have a functional and efficient laboratory information system that manages and disseminates data for use by all stakeholders at the appropriate time. In order to optimise the collection, analysis, storage and transmission of information within the laboratories, the following measures shall be implemented:

- establishing systems for data collection, use and management at all levels;
- strengthening the laboratory information system at all levels;
- strengthening interoperability between existing information systems;
- putting in place mechanisms for archiving and tracing data;
- putting in place a mechanism for collaboration and data sharing.

### VII.6. Improving the financing of laboratory activities

The sectors in charge of laboratories should plan, budget and ensure the availability of sufficient funding for the implementation of the different components of this policy.

Adequate and sustainable financing mechanisms to ensure the quality of laboratory services at all levels shall be put in place through:

- mobilisation of financial resources at the national level and within the institutions to cover both the direct and indirect costs of Quality Management System activities in the laboratory network;
- continuous reinforcement of resources allocated to the operation of public laboratories to ensure their continued compliance with standards and the achievement of their public health missions;
- the mobilisation of resources to support the operation of training institutions and continuing education programmes;
- promoting financial accessibility to quality biological analyses at all levels of the health pyramid;
- the implementation of incentives for the development and financial autonomy of laboratories;
- mobilising specific funding for external quality evaluation programmes, which will cover both the needs for setting up a system of external quality evaluation and the costs of participating in external quality evaluation;
- mobilising specific funding for supervision and mentoring activities.



## VII.7. Improving the research and cooperation framework

### VII.7.1. Research

In collaboration with institutions involved in research activities, the Ministry of Public Health should promote research and development and contribute to the improvement of health services. For this purpose, the following measures shall be applied:

- promoting and strengthening laboratory research in accordance with the national research plan;
- strengthening the capacity of laboratory personnel in the analysis and use of laboratory data for research;
- mobilising resources for biomedical research;
- conducting research, using and disseminating the results in accordance with national research and ethics policies.

### VII.7.2. Cooperation

In order to promote the signing of agreements and partnership conventions, the following actions shall be implemented:

- strengthening cooperation among sectors according to the One Health approach for the achievement of public health missions;
- strengthening collaboration among laboratories, universities and research centres;
- strengthening inter-institutional collaboration at the national level;
- Strengthening partnerships at both national and international levels.

### VII.8. Improving the framework for monitoring and evaluation of laboratory activities

Laboratory services should be monitored and evaluated continuously using clearly defined quality indicators to ensure the quality and continuous improvement of laboratory services within the national laboratory network. To this end, actions shall be directed towards:

- developing a set of quality indicators for the different levels of the laboratory network to objectively assess the quality of the services provided by the laboratories;
- developing a system for regular monitoring and evaluation of the functioning of the national laboratory network on the basis of quality indicators;
- putting in place a multi-level supervision system to ensure that all laboratories provide quality services that meet the relevant quality standards.



## VIII. IMPLEMENTATION AND MONITORING/EVALUATION MECHANISM

This section focuses on the institutional and organizational framework as well as the role of each actor in the implementation of this National Laboratory Policy.

### VIII.1. Institutional and organizational framework for implementation and monitoring/evaluation

The 2022-2030 National Laboratory Policy will be implemented at all levels of the health pyramid (central, regional and operational level) through strategic laboratory development plans valid for a period of 5 years and annual operational plans.

To this end, a national committee and regional committees for the coordination of laboratory activities will be set up by the Minister of Public Health to guarantee the implementation of the said strategic and operational plans as well as the effectiveness of the One Health approach, transparency and the participation of all the key actors of laboratory in development in Cameroon.

### VIII.2. Implementing and monitoring-evaluation bodies and structures

Coordination of the implementation and monitoring-evaluation of this policy will be ensured at all levels of the health pyramid. This coordination will be carried out by a National Laboratory Coordination Committee at the central level and by its branches at the devolved level.

#### VIII.2.1. Central level

At the central level, the Ministry of Public Health through the department in charge of laboratories in collaboration with the national laboratory coordination committee will ensure the steering, functioning, strategic monitoring, mid-term and final evaluation of the implementation of this policy.

#### VIII.2.2. Intermediate and operational levels

The Regional Delegation for Public Health (RDPH) will draw up Regional Laboratory Development Plans with the support of the National Laboratory Network Coordination Committee.

**NB:** All these coordination bodies and structures will ensure that civil society organizations and associations, actors of the private health sector, ministries concerned by the One Health approach and TFPs are involved at all levels for joint decision-making on laboratory issues.

### VIII.3. Major actors and their role

#### VIII.3.1. Government

The Government is in charge of the achievement of the objectives of this policy. It will validate, adopt and ensure its implementation under the leadership of the MOH, which is the project manager. It will also give general guidelines for the implementation and mobilize the necessary funding for the execution of this policy in all the ministries involved in its implementation.

The MOH will manage the resources made available to it for the achievement of the objectives of this policy, play the role of regulator and technical leader in the sector, then shall coordinate at the technical level all the interventions geared towards the achievement of the projected objectives.

The national laboratory coordination committee will inform the Ministry of Public Health of the progress of the implementation of this policy, through bi-annual performance reports.

#### VIII.3.2. Role of other actors in the health system

Regional and local authorities with the support of devolved structures of the State will work in synergy at the operational level for the strengthening of technical platforms as well as the development and implementation of the various plans which execute this policy.

### VIII.4. Implementation and monitoring-evaluation methods of the national laboratory policy

This policy will be implemented through three (4) major tools:

- the National Strategic Laboratory Development Plan;
- the National Quality Strategy plan;
- Regional Laboratory Development Plans;
- Operational Laboratory Development Plans.

#### **VIII.4.1. Monitoring and evaluation of the implementation**

Monitoring and evaluation will be ensured through a strategic results framework that presents the quantitative goals and objectives of the strategy.

#### **VIII.4.2. Evaluation**

The mid-term evaluation of this document will be done midway and then in 2030; this will enable to assess the progress of results obtained as well as identifying bottlenecks that prevented the targets from being achieved.



## REFERENCES

- [1] ISO 15189 : 2012 - medical analysis laboratory: requirements for quality and competence
- [2] National laboratoeies biosafety and biosecurity guidance in Cameroon, 2019
- [3] ISO/IEC 17000 : 2020- Conformity Assessment - Vocabulary and Principles
- [4] <https://www.who.int/fr/news-room/questions-and-answers/item/one-health>
- [5] Health Sector Strategy, 2016-2027
- [6] Finance law 2021
- [7] BUCREP, 3e RGPH : projections démographiques, Volume 03 Tome 03, in <http://www.bucrep.cm/>
- [8] National Institute of Statistics (INS), Cameroon Household Survey (ECAM 4), conducted in 2014
- [9] Number of refugees, [https://www.iccpportal.org/system/files/plans/FINAL %20COPY%20PSNPL-Ca%20FRENCH.pdf](https://www.iccpportal.org/system/files/plans/FINAL_%20COPY%20PSNPL-Ca%20FRENCH.pdf)
- [10] Ministry of Public Works, Cameroon Road Network, 2020
- [11] Maputo declaration, 2008
- [12] National Strategic Plan for Laboratory Development, 2018-2022
- [13] Guidance for Integrated Disease Surveillance and Response
- [14] Guidance document for development of district and peripheral laboratory services to support universal health coverage (WHO-AFRO, 2019)
- [15] Guidance for establishing a national laboratory framework first edition 2021, Africa CDC/Africa Union



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## APPENDIX 2:

# The Maputo Declaration on Strengthening of Laboratory Systems

We, representatives of Governments, multilateral agencies, development partners, professional associations, and academic institutions, participated in a Consensus Meeting on Clinical Laboratory Testing, Harmonization and Standardization in Maputo, Mozambique, on 22nd - 24th January 2008. The meeting sought to address laboratory challenges that limit the scale-up of services for tuberculosis, malaria and HIV diagnosis and care.

The objectives of the Maputo meeting were:

- To review and agree on a list of supplies and tests needed at each level of an integrated tiered laboratory network;
- To develop a consensus to guide standardization of laboratory equipment at each level of the laboratory network;
- To develop a consensus on key considerations to guide maintenance and service contracts for equipment at various levels of the laboratory network.

**Recognize** the burden of the priority diseases HIV, malaria and tuberculosis. Globally, some 33.2 million individuals are living with HIV but of those just 10% are aware of their sero-status<sup>1</sup>. In spite of efforts to limit transmission, the incidence of HIV infection remains high. Similarly, 8.8 million new cases of tuberculosis occur annually while the prevalence of multi- and extensively-drug resistant tuberculosis continues to increase with only a fraction of cases being detected<sup>2</sup>. Co-infection with HIV and tuberculosis remains a difficult clinical challenge in many settings. In many countries, malaria remains the largest contributor to mortality primarily among infants and children, with about 1 million deaths per year<sup>3</sup>.

**Recognize** the need to expand and further develop quality-assured laboratory services as part of a greater framework of health system strengthening within resource-limited settings. Increasingly, countries and implementing partners have identified that limited laboratory capacity represents a major barrier to implementation and sustainability of prevention, treatment and care programs for HIV, malaria and tuberculosis.

**Recognize** that in resource-limited settings, several challenges have resulted in inadequate laboratory systems to support the scale-up of programs. These include a lack of leadership and advocacy, human resources, career path and retention of staff, national laboratory policy, strategic planning (budgetary concerns), insufficient physical infrastructure, supply chain management, and quality management systems (quality assurance).

Note that there has been a substantial increase in funding to fight HIV, tuberculosis, and malaria. For instance, a total contribution of US\$10 billion per annum has been secured from donors towards prevention, treatment and care programs for the three diseases through funding bodies such as the Global Fund to fight AIDS, Tuberculosis and Malaria, The US Presidents Emergency Plan for AIDS Relief, US President's Malaria Initiative, the World Bank, and the Bill and Melinda Gates Foundation. This represents a significant increase on previous commitments that totaled US\$1 billion in 2001 for disease control programs for high burden diseases in resource-limited settings.

**Recognize** that in order to improve and sustain access to laboratory services, there must be an integration of laboratory support for tuberculosis, malaria and HIV disease programs. The aim of this effort should be to sustain any improvements made to a laboratory as part of the greater health system from a public health perspective.

**Call** on national governments to support laboratory systems as a priority by developing a national laboratory policy within the national health development plan that will guide the implementation of a national strategic laboratory plan. Governments should establish a department of laboratory systems within the Ministry of Health.

**Call** on national governments with support of their donors and partners in resource-limited settings to develop national strategic laboratory plans that integrate laboratory support for the major diseases of public health importance including HIV, tuberculosis, and malaria.

<sup>1</sup> Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO) 2007 AIDS Epidemic Update Accessible sur [http://data.unaids.org/pub/EPISlides/2007/071119\\_epi\\_pressrelease\\_en.pdf](http://data.unaids.org/pub/EPISlides/2007/071119_epi_pressrelease_en.pdf) du 24 janvier 2008  
<sup>2</sup> WHO fact sheet no. 104 - Tuberculosis  
Accessible on <http://www.who.int/mediacentre/faon> sur <http://www.who.int/malaria/faq.html> of the 24 January 2008

## **APPENDIX 1:**

### **Legal framework of laboratory activities**

#### **Laws**

- Law No. 96/03 of 4 January 1996 on the framework law in the field of health;
- Law No. 96/12 of 5 August 1996 relating to environmental management;
- Law No. 2000/17 of 19 December 2000, to regulate veterinary health inspection;
- Law No. 2001/014 of 23 July 2001 relating to seed activity;
- Law No. 2003/003 of 21 April 2003 on phytosanitary protection;
- Law No. 2003/007 of 10 July 2003 to govern the activities of the fertilizer sub-sector in Cameroon.

#### **Decrees**

- Decree No. 80/240 of 30 June 1980 on the reorganization of the Centre Pasteur of Cameroon;
- Decree No. 83/479 of 8 October 1983 to establish the National Veterinary Laboratory (LANAVET);
- Decree No. 90-1465 of 9 November 1990 to set the terms for the creation and operation of private medical analysis laboratories.
- Decree No. 90/460 of 8 November 1990 to reorganize the National Veterinary Laboratory;
- Decree No. 92/252/PM of 6 July 1992 to lay down conditions and procedures for the creation and opening of some private health facilities;
- Decree No. 450/ PM of 22 October 1998 to lay down the procedures for the approval of pharmaceutical products;
- Decree No. 2005/0770/PM of 6 April 2005 to lay down the conditions for phytosanitary control;
- Decree No. 2005/0771/PM of 6 April 2005 to lay down the conditions for the execution of plant quarantine operations;
- Decree No. 2005/0772/PM of 6 April 2005 to lay down the conditions for the approval and control of phytosanitary products;
- Decree No. 2005/099 of 6 April 2005 to organize the Ministry of Wildlife and Forestry;
- Decree No. 2005/118 of 15 April 2005 to organize the Ministry of Agriculture and Rural Development;
- Decree No. 2010/2952/PM of 1 November 2010 to create, organize and lay down the functioning of the National Public Health Observatory;
- Decree No. 2012/382 of 14 September 2012 to organize the Ministry of Livestock, Fisheries and Animal Industries;

- Decree No. 2012/2809/PM of 26 September 2012 to lay down the conditions for sorting, collection, storage, transport, recovery, recycling and final disposal of waste;
- Decree No. 2012/431 of 1 October 2012 to organize the Ministry of the Environment, Nature Protection and Sustainable Development;
- Decree No. 2013/093 of 3 April 2013 to organize the Ministry of Public Health;
- Decree No. 2019/067 of 12 February 2019 to organize and lay down the functioning of the National Centre for Blood Transfusion.

#### **Orders**

- Order No. 003/MINEPDED of 15 October 2012 to lay down specific conditions for the management of medical and pharmaceutical waste;
- Joint order No. 005/MINEPDED/MINCOMMERCE of 24 October 2012 to lay down specific conditions for the management of electrical and electronic equipment, as well as the disposal of waste from this equipment;
- Order No. 2964/MINSANTE of 9 October 2013 to create, organize and lay down the functioning of the National Public Health Laboratory (NPHL);
- Order No. 028/CAB/PM OF 4 April 2014 to create, organize and lay down the functioning of the National Program for the prevention and fight against emerging and re-emerging Zoonoses;

#### **Decisions**

- Decision No. 0496 /D/MINSANTE/DPM of 3 June 2009 making public in Cameroon the guide for the proper execution of medical biology analyses;
- Decision No. 0817 /MINSANTE/CAB/S-G/DLM/DAJC of 11 June 2012 to create, organize and lay down the functioning of regional centres for the prevention and control of epidemics;
- Decision No. 0498D/MINSANTE/SG/CN-LS/GTC/SP of 4 April 2019 to lay down conditions for access to and monitoring of populations in HIV screening and management services in public health facilities and their affiliated community based organizations.



**Call** on donors and implementing partners to ensure that in supporting laboratory strengthening that proper consideration is given to fostering national ownership.

**Call** on countries and all partners to urgently address the broader laboratory human resources agenda for laboratory strengthening including training, recruitment and retention of laboratory workers and their adequate financing.

**Call** on donors and development partners to commit to work collaboratively with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated national laboratory network. These laboratory strengthening efforts should seek to build public private partnerships.

**Call** on academic institutions and research funders to accelerate efforts to develop new diagnostic tools applicable to resourced-limited settings.

Done in Maputo, Mozambique on 24 January 2008

